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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,641	09/29/2004	Christian Drohmann	53383	4300

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EXAMINER	
POPOVICS, ROBERT J	
ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,641	DROHMANN ET AL.	
	Examiner	Art Unit	
	/Robert James Popovics/	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,13-15,19-22 and 28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,13-15,19-22 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicants' election without traverse is noted:

> In compliance with the requirements of 37 C.F.R. §1.143, applicants provisionally elect group 1, "Polyolefins" of the "A" species and group 5 "Crosslinked Polyvinyllactams" of the "B" species. Claims 11 – 27 are readable on the elected species. This provisional election is submitted without traverse.

Claim Rejections - 35 USC § 112

Claims **11,13-15,19-22** and **28** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims **11,13-15,19-22** and **28** fail to specify **"melt"** extrusion or the fact that the PVP used is **"insoluble."** Given the arguments presented by Applicants, it has become clear that both of these limitations are essential to the practice of the invention, and that absent their recitation, the claims are incomplete.

Claim Rejections - 35 USC § 103

Claims **11,13-15,19-22** and **28** are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of **Butterworth (US 3,958,023)** and/or **Van Den Eynde (US 6,117,459)** and/or **BASF's "60th Anniversary of Povidone" and/or Wedlock (US 5,665,369)** and/or **AAPA (Applicants' Admitted Prior Art).**

Butterworth discloses the use of **PVPP** admixed with conventional filter aids to treat liquids. (see column 2 and claims 1 and 4 of **Butterworth**).

BASF ExAct page 4 – No.2, July 1999

More densely crosslinked PVP is prepared by copolymerisation of N-vinylpyrrolidone with bifunctional monomers. Because of the combination of high water uptake and insolubility, swelling is observed with crosslinked PVP when exposed to water while soluble PVP simply dissolves.

The popcorn polymerisation – bulk polymerisation of N-vinylpyrrolidone either in presence of alkali metal hydroxide above 100°C or in presence of small amounts of bifunctional monomers at 100°C – leads to highly crosslinked PVP particles with a specific surface area of a few square meters per gram. This popcorn PVP, Crospovidone, finds important use as tablet disintegrant, as an agent for clarifying beverages and as active ingredient for stomach and gastrointestinal diseases. In contrast to soluble PVP, complexes of crosslinked PVP with high complexation constants enable the extraction of the complexed molecule. The usefulness of crosslinked PVP for gastrointestinal diseases is based on the following properties:

[illegible]

Complex formation of crosslinked PVP with tannin is of interest both in pharmacology and in beverage technology [illegible]. Tannin is a biopolymer with polyphenol structures. The complexation constant of tannin with Kollidon CL is >1000 L mol^{-1} (in 0.1 N hydrochloric acid).

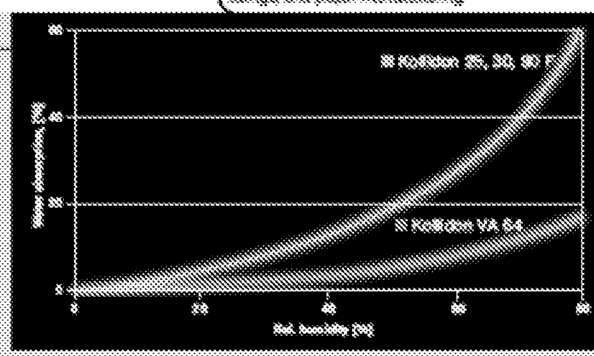
Particle size distribution plays a more crucial role for the application properties of crosslinked PVP as compared to soluble grades. The properties of Kollidon grades as a disintegrant for tablets vary with particle size (Table 3) [illegible]. In tablets obtained from Kollidon by compression the disintegration time decreases with the particle size of the PVP used for the formulation. Like soluble PVP, Kollidon CL-M is capable of stabilizing suspensions, such as antibiotics, antacids, vitamin preparations and topical formulations.

Lately, it has been demonstrated, that pH-controlled drug release is possible from PVP/Polyacrylic acid interpenetrating networks [illegible]. Radiation cured hydrogels of PVP, polyethylene glycol, and agar have many desirable properties for using as wound dressings [illegible].

Properties of insoluble PVP grades (Table 3)

Property	Crospovidone	Kollidon CL	Kollidon CL-M	[illegible]
Particle size [illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Bulk density	[illegible]	[illegible]	[illegible]	[illegible]
Specific surface area [illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

Hygroscopicity of Kollidon VA 64 and Kollidon 25, 30 or 90 F for comparison, after 7 days at 25 °C (Figure 4)

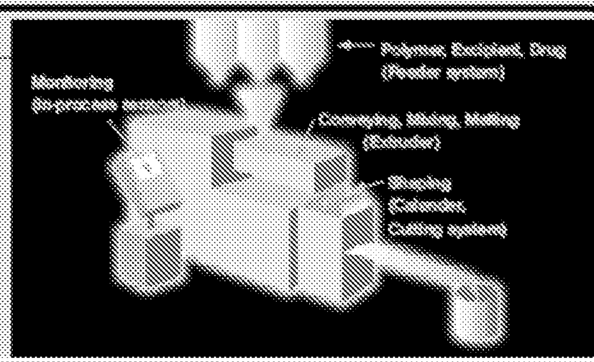


3 Polymer/Drug Melt Extrusion

As a result of close collaboration over the past ten years, Knoll AG and its parent company BASF have developed a patent-protected novel pharmaceutical manufacturing technology: drug is incorporated by melt extrusion in a matrix consisting of a pharmaceutical polymer. Due to its thermoplasticity and balanced aqueous solubility properties, Kollidon grades have been found to provide a comprehensive and universal base for various types of drugs. After melt extrusion, the active drug can be present in the extrudate in one or two forms: as a crystal suspended in the hardened Kollidon matrix, or as a molecule dissolved in the polymer during the melting phase and remaining dissolved in the finished product – a "solid solution". Melt extrusion technology paves the way for benefits in therapy (Figure 5):

[illegible]

Polymer/Drug Melt Extrusion: Product is either tablet, granules, pellet, sheet... (Figure 5)



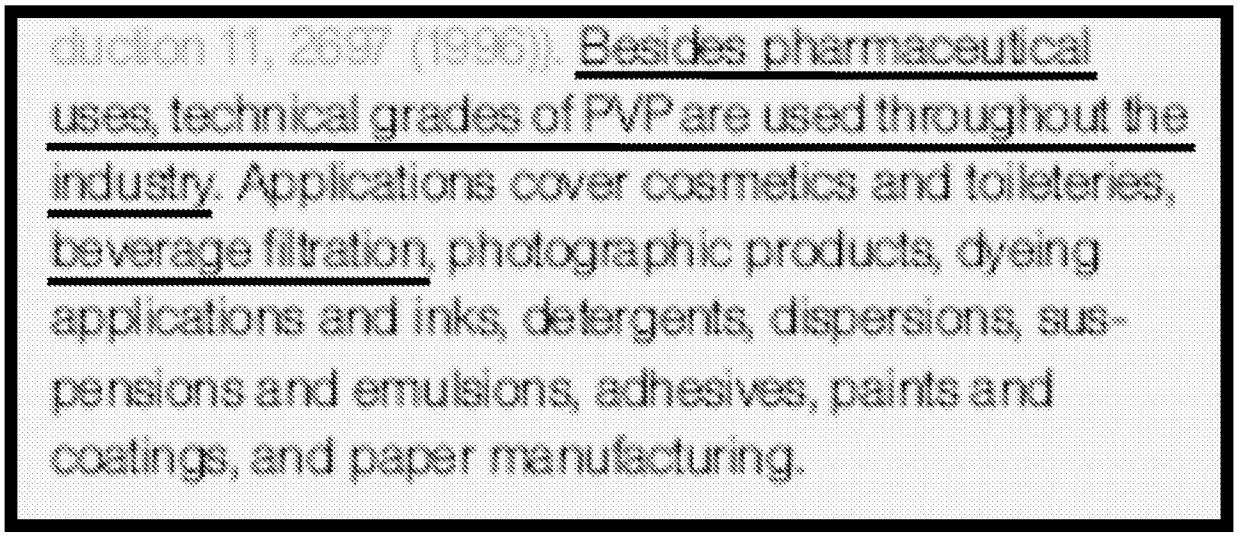
Miscellaneous Applications

ther pharmaceutical, biomedical and biochemical a pplications cover protein isolation and protein stabilization [illegible]. Besides pharmaceutical u ses, technical grades of PVP are used throughout the i ndustry. Applications cover cosmetics and toiletries, b everage filtration, photographic products, dyeing a pplications and inks, detergents, dispersions, susp ensions and emulsions, adhesives, paints and c oatings, and paper manufacturing.

Van Den Eynde (US 6,117,459) discloses the use of **polyolefins**, for example, **polypropylene** and **polyethylene** (see **claim 8** of **Van Den Eynde**) and **PVPP** (see **claim 12** of **Van Den Eynde**) in the treatment of **beer**. **Van Den Eynde,** like **Butterworth**, teaches that it is preferred that the filtration and stabilization steps be carried out simultaneously. See **column 4, lines 45-55** of **Van Den Eynde**:

> In one preferred embodiment of the invention, the process further includes a stabilization step. This step can be carried out during or after the filtration step proper, using filtration adjuvants conventionally employed, including silica gels, gallic tannins, etc. If the stabilization is carried out after the filtration, proteolytic enzymes and polyvinylpyrrolidone (PVPP) are generally used, preferably in a form that can be regenerated.
>
> The stabilization is advantageously carried out concomitantly with the filtration.

BASF's "60th Anniversary of Povidone" published in **July of 1999**, teaches the melt extrusion (i.e., **"compounding"**) of **PVPP** with other compounds. **Beverage treatment applications are clearly mentioned under a section labeled "Miscellaneous Applications," as indicated in the annotated copy of page 4 above**:


duction 11, 2897 (1996). Besides pharmaceutical uses, technical grades of PVP are used throughout the industry. Applications cover cosmetics and toiletries, beverage filtration, photographic products, dyeing applications and inks, detergents, dispersions, suspensions and emulsions, adhesives, paints and coatings, and paper manufacturing.

In view of **BASF's "60th Anniversary of Povidone,"** it would have been obvious to one skilled in the art to melt extrude (i.e., compound/mix) known filtration aids, such as the polyolefins, polypropylene or polyethylene taught by **Van Den Eynde**, for example, with **PVPP,** to practice the invention of **Butterworth** and/or **Van Den Eynde**, in order to obtain the benefits **Butterworth** extols:

ABSTRACT

The present invention provides an improved process for increasing the chill haze stability of aqueous liquids derived from fruits and vegetables, (e.g., beer, wine, fruit juices, vinegar, etc.) by **using one or more haze control agents in a precoat or after precoat layer in the filter media used to filter the liquid and by adding one or more haze control agents as a body feed upstream of the filter**. In a preferred embodiment one or more haze control agents are also added in ruh storage at a time in the process significantly before the filtration step. **This improved process permits the beverage to be packaged immediately after filtration, thus eliminating the time consuming and space consuming storage following filtration normally required by conventional chill haze control techniques.**

in addition, that **Van Den Eynde** teaches is preferred. Both **Van Den Eynde** and **Butterworth** clearly teach that is desirable/preferred to perform the filtration and stabilization in a single step.

The huge ranges of percentages claimed cover almost the entirety of possibilities. Absent a showing of criticality or unexpected result specifically associated the extremely broad ranges claimed, the selection of any combination of percentages would have been readily apparent to the skilled artisan, given the teachings of these references.

Wedlock teaches the melt extrusion of PVP with active ingredients followed by subsequent milling. In view of the teachings of **Wedlock**, it would have been obvious to one skilled in the art to melt extrude (i.e., compound/mix) known filtration aids (as taught by **AAPA** for example) or active ingredients, such as the polyolefins, polypropylene or polyethylene taught by **Van Den Eynde**, for example, with **PVPP,** to practice the invention of **Butterworth** and/or **Van Den Eynde**, in order to obtain the benefits **Butterworth** extols as set forth above.

Response to Arguments

Applicants' arguments with respect to claims **11,13-15,19-22** and **28** have been considered but are moot in view of the new ground(s) of rejection.

The arguments are largely rendered moot by the new grounds of rejection.

The Examiner does not find the majority of arguments made by Applicants' persuasive. Several of the arguments continue not to be commensurate in scope with the claims. For example, reference is made to **"melt extrude"** beginning at page 6, lines 20-21 of the Remarks of 9/24/09, yet the claims do not specify **"melt"** extrusion, but simply extrusion. Additionally, it is noted that the **"insoluble"** nature of PVP is not recited in the claims, yet lies at the heart of Applicants' arguments.

All of these arguments are moot. **Anniversary** clearly teaches melt extrusion, primarily in the context of a pharmaceutical application, while at the same time on the same page before and after the discussion of melt extrusion, discussing **beverage treatment applications**. One skilled in the beverage treatment would have easily made the logical leap, and readily appreciated that the same melt extrusion process could be used to make beverage treatment compositions. Why else would beverage treatment applications twice be mentioned on that page?

It is submitted that the balance of the arguments are moot in view of the new grounds of rejection. This action is **NOT FINAL.**

Any inquiry concerning this communication should be directed to /Robert James Popovics/ at telephone number (571) 272-1164.

/Robert James Popovics/
Primary Examiner
Art Unit 1797